PATENT

Attorney Docket No. 24286

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

SAVITZKY et al.

Examiner: P. Mertz

Serial No.: 09/599,400

Art Unit: 1646

Filed: June 22, 2000

For: **VARIANT OF TNF-RECEPTOR**

RESPONSE TO RESTRICTION REQUIREMENT

Commissioner for Patents
Washington, D.C. 20231

Sir:

This is in response to the Office Action dated September 29, 2000, due for reply by October 29, 2000. This response is filed with a Petition for a One-Month Extension of Time and the required fee under 37 C.F.R. § 1.136(a) extending the due date to November 29, 2000.

SUMMARY OF RESTRICTION REQUIREMENT

The Examiner has required applicant under 35 U.S.C. 121 to elect a single Group from the following:

I: Claims 1-2, 5, 9-15, drawn to a splicing variant of tumor necrosis factor receptor protein, an expression vector, and a host cell, classified in class 536, subclass 23.5.

II: Claims 3-4, 12-15, drawn to a splicing variant of tumor necrosis factor receptor protein, classified in class 530, subclass 350.

III: Claims 6-8, 14-15, drawn to an antibody to a splicing variant of tumor necrosis factor receptor protein, classified in class 530, subclass 387.1.

IV: Claims 16-17, 18-21, drawn to a method of detecting the presence of a nucleic acid encoding a splicing

variant of tumor necrosis factor receptor protein in a sample, classified in class 435, subclass 6.

V: Claims 22-24, drawn to a method of identifying candidate compounds capable of binding a splicing variant of tumor necrosis factor receptor protein, classified in class 435, subclass 7.1.

VI: Claim 25, drawn to an agonist of a splicing variant of tumor necrosis factor receptor protein, class and subclass undeterminable.

VII: Claim 26, drawn to an antagonist of a splicing variant of tumor necrosis factor receptor protein, class and subclass undeterminable.

VIII: Claims 27-30, drawn to a method of determining a splicing variant of tumor necrosis factor receptor protein in a sample using an antibody, classified in class 435, subclass 7.1.

As the basis for this restriction requirement, the Examiner contends that the inventions are distinct, each from the other, for the following reasons:

> Applicants are advised that claims 12-15 are improper Markush claims because the multiple elements recited therein are polypeptides, antibodies and nucleic acids, which do not share a common technical feature which is based on a common property or special technical feature not found in the prior art. These polypeptides, antibodies and nucleic acids are independent and distinct chemical compounds lacking either a common structural property which distinguishes them as a group from structurally related compounds of the prior art or which provides them with a common utility which is lacking from those prior art polypeptides or nucleic acids.
> Inventions I-VIII are distinct, each from the other because of the following reasons:
> Inventions I-III are independent and distinct, each from the other, because they are products which possess characteristic differences in structure and function and each has independent utility, that is distinct for each invention which cannot be exchanged. The nucleic acid of Group I can be used to make a hybridization probe or can be used in gene therapy as well as in the production of the protein of interest. The protein of Group II can be used other than to make the antibody of Group III, such

as used as a probe, or used therapeutically or diagnostically (e.g. in screening). Although the antibody of Group III can be used to obtain the nucleic acid of Group I, it can also be used in diagnostics (e.g. as a probe in immunoassays, or in immunochromatography) or it may be used therapeutically.

Inventions I and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product of invention I can also be used in gene therapy or in recombinant production of the protein of interest.

Inventions III and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product of invention III can also be used in immunoaffinity chromatography.

Inventions II and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product of invention I can also be used as an antigen in the production of antibodies.

Inventions I, V-VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together.

Inventions II and IV, VI-VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP §

806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together.

Inventions III and IV-VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together.

Inventions VI and IV-V, VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together.

Inventions VII and IV-V, VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together.

Inventions IV-V and VIII are independent and distinct, each from the other, because the methods are practiced with materially different process steps for materially different purposes and each method requires a non-coextensive search because of different starting materials, process steps and goals.

Having shown that these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their recognized divergent subject matter as defined by MPEP § 808.02, the Examiner has *prima facie* shown a serious burden of search (see MPEP § 803). Therefore, an initial requirement of restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CAR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR § 1.48(b) if one or

more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventor ship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CAR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CAR 1.821 through 1.825 for the reason(s) set forth on the attached Notice to Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

As the basis for requiring this restriction/election, the Examiner has provided that the above groups are patentably distinct because they are products which possess characteristic differences in structure and function, are related as product and process of use, are unrelated, and/or are independent and distinct, each from the other.

ELECTION

Applicants provisionally elect with traverse Group I (Claims 1-2, 5, 9-15, drawn to a splicing variant of tumor necrosis factor receptor protein, and expression vector, and a host cell, classified in class 536, subclass 23.5.)

TRAVERSAL

Applicants respectfully traverse the Examiner's restriction requirement for the following reasons.

The restriction requirement is improper because it omits "an

appropriate explanation" as to the existence of a "serious burden" if a restriction were not required. (MPEP § 803, Revision 14, November 1992). An examination of all the claims in this application would not pose a serious burden because a search of any one of invention Groups I and II would require searching the prior art areas appropriate to the other invention Group.

At a minimum, applicants respectfully request the Examiner to combine Groups I and II for examination purposes. Given their overlapping subject matter, examination of these two inventive Groups would not pose a serious burden because they would be coextensive.

Groups I and II are directed to sequences coding for a splicing variant of the tumor necrosis receptor protein , with the claims of Groups I being directed to nucleic acid sequences, and the claims of Group II being directed to amino acid sequences. Once a nucleic acid sequence is given, a single amino acid sequence is coded thereby. Although the reverse is not true (due to the degenerative nature of the genetic code), applicants propose deletion of claim 5, directed to any nucleic acid coding for the amino acid, and maintenance only of the nucleic acid of claim 1 if the Examiner agrees to combine the inventions of Groups I and II. Accordingly, applicants would only claim the nucleic acid sequences which are depicted in the sequence listing.

Applicants further point out it appears as though the Examiner would hold obvious an application directed to the amino acid if the nucleic acid is known (and vice versa). Since there is a direct inseparable connection between the two, applicants maintain Groups I and II should be combined and viewed as a single invention.

Lastly, it is important for the Examiner to understand that applicants have paid a filing fee for an examination of all the claims in this application. If the Examiner refuses to examine the claims paid for when this application was filed, applicants must pay duplicative fees to file a divisional application for the non-elected or withdrawn claims.

In view of the foregoing, applicants respectfully request the Examiner to reconsider and withdraw the restriction requirement and requirement for election of a species and allow all claims pending in this application.

Regarding the Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures, applicants respectfully point out to the Examiner that the requisite "Sequence Listing" in computer readable form was properly submitted as required by 37 C.F.R. § 1.821(e) on June 22, 2000 at the time of filing the present application. A copy of the stamped filing receipt is enclosed for the Examiner's review. However, a second copy of the "Sequence Listing" in

computer readable form is enclosed herein on the attached diskette for the Examiner's convenience.

CONCLUSION

If the Examiner has any questions or wishes to discuss this matter, the Examiner is welcomed to telephone the undersigned attorney.

Respectfully submitted,

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